

Applicant: Faour et al.

Amendments to the Claims

Docket No. PHUS-28

CLAIMS

We claim:

- 1) (Canceled)
- 2) (Canceled)
- 3) (Canceled)
- 4) (Canceled)
- 5) (Canceled)
- 6) (Canceled)
- 7) (Canceled)
- 8) (Canceled)
- 9) (Canceled)
- 10) (Canceled)
- 11) (Currently amended) The pharmaceutical [~~dosage-form~~] ~~composition~~ of claim 49, wherein the [~~dosage-form~~] ~~composition~~ is selected from the group consisting of a gel, cream, ointment, pill, tablet, capsule, liquid, suspension, osmotic device, bead, granule, spheroid, particulate, paste, prill, reconstitutable solid, powder, caplet, agglomerate, granulate, suppository, enema, bar, plate, pill, and injectible liquid.
- 12) (Currently amended) The pharmaceutical [~~dosage-form~~] ~~composition~~ of claim 49, wherein the COX-II inhibitor is released at a faster rate than pridinol, or the COX-II inhibitor is released at a slower rate than pridinol.
- 13) (Currently amended) The pharmaceutical [~~dosage-form~~] ~~composition~~ of claim 49, wherein the [~~dosage-form~~] ~~composition~~ provides therapeutically effective plasma levels of the COX-II inhibitor for a period up to at least about 12 hours after administration to a mammal.
- 14) (Currently amended) The pharmaceutical [~~dosage-form~~] ~~composition~~ of claim 49, wherein after administration to a mammal the [~~dosage-form~~] ~~composition~~ provides therapeutically effective plasma levels of pridinol for a period of administration sufficient to enhance the therapeutic benefit provided by the COX-II inhibitor.
- 15) (Currently amended) The pharmaceutical [~~dosage-form~~] ~~composition~~ of claim 49, wherein the pharmaceutical [~~dosage-form~~] ~~composition~~ is adapted for oral, buccal, ocular, otic, gastrointestinal, dermal, rectal, vaginal, cervical, intrauterine, epidermal, transdermal, implant, mucosal, parenteral, sublingual, nasal, or pulmonary delivery.
- 16) (Canceled)

Applicant: Faour et al.

Amendments to the Claims

Docket No. PHUS-28

- 17)(Canceled)
- 18)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein the dosage form provides therapeutically effective levels of each drug for a period of at least 12 hours after administration to a ~~[subject]~~ mammal .
- 19)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 18, wherein the period is about 12 to 60 hours.
- 20)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 19, wherein the period is about 12 to 30 hours.
- 21)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 19, wherein the period is about 18 to 48 hours.
- 22)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein after administration to a ~~[subject]~~ mammal the plasma level of the COX-II inhibitor or pridinol is dependent upon the plasma level of pridinol or COX-II inhibitor, respectively.
- 23)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein after administration to a ~~[subject]~~ mammal the plasma level of the COX-II inhibitor or pridinol is independent of the plasma level of pridinol or COX-II inhibitor, respectively.
- 24)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein the ~~[dosage form]~~ composition provides therapeutic plasma levels for pridinol in an amount sufficient to provide a therapeutic benefit to a ~~[subject]~~ mammal to whom it is administered.
- 25)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein after administration to a mammal the ~~[dosage form]~~ composition provides therapeutic plasma levels for the COX-II inhibitor in the range of about 90 ng to about 300 ng per ml of plasma in the ~~[subject]~~ mammal .
- 26)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein the COX-II inhibitor and pridinol are released sequentially after exposure to an aqueous environment.
- 27)(Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein the COX-II inhibitor and pridinol are released concurrently after exposure to an aqueous environment.

Applicant: Faour et al.

Amendments to the Claims

Docket No. PHUS-28

- 28)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 49, wherein the COX-II inhibitor and pridinol are released in spaced apart periods of time after exposure to an aqueous environment.
- 29)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 49, wherein each drug is independently released according to a controlled, sustained, timed, targeted, pseudo-first order, first order, pseudo-zero order, or zero-order release profile after exposure to an aqueous environment, optionally wherein the release of one or both of the drugs begins after expiration of a lag period, and optionally wherein the release of one drug begins after release of the other drug has begun.
- 30)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 49, wherein the ~~[dosage-form]~~ composition provides a controlled release of the COX-II inhibitor and a controlled release of pridinol after exposure to an aqueous environment.
- 31)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 49, wherein the ~~[dosage-form]~~ composition provides a controlled release of the COX-II inhibitor after exposure to an aqueous environment and a release of pridinol within two hours after exposure to an aqueous environment.
- 32)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 49, wherein the ~~[dosage-form]~~ composition provides a controlled release of pridinol after exposure to an aqueous environment and a release of the COX-II inhibitor within two hours after exposure to an aqueous environment.
- 33)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 49, wherein the ~~[dosage-form]~~ composition releases the COX-II inhibitor and pridinol within two hours after exposure to an aqueous environment.
- 34)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 49, wherein the ~~[dosage-form]~~ composition releases pridinol within two hours after exposure to an environment of use and release of the COX-II inhibitor begins after release of pridinol has begun.
- 35)(Currently amended) The pharmaceutical ~~[dosage-form]~~ composition of claim 34, wherein the ~~[dosage-form]~~ composition provides a controlled release of the COX-II inhibitor after exposure to an aqueous environment.

Applicant: Faour et al.

Amendments to the Claims

Docket No. PHUS-28

- 36) (Currently amended) The pharmaceutical [~~dosage form~~] ~~composition~~ of claim 49, wherein the [~~dosage form~~] ~~composition~~ releases the COX-II inhibitor within two hours after exposure to an environment of use, release of pridinol begins after release of the COX-II inhibitor has begun.
- 37) (Currently amended) The pharmaceutical [~~dosage form~~] ~~composition~~ of claim 36, wherein the [~~dosage form~~] ~~composition~~ provides a controlled release of pridinol after exposure to an aqueous environment.
- 38) (Canceled)
- 39) (Canceled)
- 40) (Canceled)
- 41) (Canceled)
- 42) (Canceled)
- 43) (Canceled)
- 44) (Canceled)
- 45) (Canceled)
- 46) (Canceled)
- 47) (Canceled)
- 48) (Canceled)
- 49) (Currently amended) A pharmaceutical [~~dosage form~~] ~~composition~~ comprising:
- a) a COX-II inhibitor selected from the group consisting of rofecoxib and celecoxib;
 - b) pridinol; and
 - c) at least one pharmaceutical excipient.
- 50) (Currently amended) The pharmaceutical [~~dosage form~~] ~~composition~~ of claim 49, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbent, alkalizing agent, antioxidant, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.
- 51) (Currently amended) The [~~dosage form~~] ~~composition~~ of claim 49, the weight ratio of COX-II inhibitor to pridinol varies from (12.5:2.2) to (50:8).

Applicant: Faour et al.

Amendments to the Claims

Docket No. PHUS-28

- 52) (Currently amended) The ~~[dosage form]~~ composition of claim 49, wherein the COX-II inhibitor and pridinol are independently provided in each occurrence in controlled release form, sustained release form, timed release form, or in a form wherein complete release of drug occurs within two hours of beginning of its release.
- 53) (Currently amended) The ~~[dosage form]~~ composition of claim 52, wherein release of at least the COX-II inhibitor~~;~~ or pridinol~~;~~ ~~or both~~ begins after expiration of a lag period and/or release of at least ~~[one of]~~ the COX-II inhibitor ~~[and]~~ or pridinol is targeted in a mammal to which the composition is administered.
- 54) (Currently amended) The ~~[dosage form]~~ composition of claim 49, wherein the COX-II inhibitor~~;~~ and pridinol~~;~~ ~~or both~~ are independently provided in each occurrence in pseudo-first order, first order, pseudo-zero order, or zero order release form.
- 55) (Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein the COX-II inhibitor and pridinol are released according to different release profiles when the dosage form is exposed to an aqueous environment.
- 56) (Currently amended) The pharmaceutical ~~[dosage form]~~ composition of claim 49, wherein the COX-II inhibitor is released at approximately the same rate as pridinol when the dosage form is exposed to an aqueous environment.

Docket No.: PHUS-28
FAOUR ET AL.

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CURRENT CLAIM STATUS	PROPOSED ORDER OF CLAIMS FOR ISSUANCE	PROPOSED CLAIM NUMBERS FOR ISSUANCE
1. Canceled	49	1
2. Canceled	11	2
3. Canceled	15	3
4. Canceled	12	4
5. Canceled	13	5
6. Canceled	18	6
7. Canceled	19	7
8. Canceled	20	8
9. Canceled	21	9
10. Canceled	14	10
11.	24	11
12.	25	12
13.	22	13
14.	23	14
15.	26	15
16. Canceled	27	16
17. Canceled	28	17
18.	29	18
19.	30	19
20.	31	20
21.	32	21
22.	33	22
23.	34	23
24.	35	24
25.	36	25
26.	37	26
27.	52	27
28.	53	28
29.	54	29
30.	55	30
31.	56	31
32.	50	32
33.	51	33
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38. Canceled		
39. Canceled		
40. Canceled		
41. Canceled		

Docket No.: PHUS-28
FAOUR ET AL.

10/770,901
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42. Canceled			
43. Canceled			
44. Canceled			
45. Canceled			
46. Canceled			
47. Canceled			
48. Canceled			
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